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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,300	04/09/2001	Hans R. Brunner	SSM-487US	2492

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	12

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,300	BRUNNER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *19-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Newly submitted claims 19-27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Independent claims 1, 13 and 14 are directed to a device/ method of use of a device not requiring a pressure control means and newly submitted independent claim 19 is directed to a device comprising a pressure control means.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. Claims 1, 2 and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Barak et al. (US 6494852). Gardner et al. disclose a medical appliance for intermittently pulsed compression of proximal joint and adjacent tissue of the human body.

As related to claim 1, the readily portable medical appliance for intermittent compression of human extremities, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that

converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elebow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As to the cuff pressure, the cuff pressure is selective and ranges between atmospheric/ deflated pressure levels to 200 mm Hg with a suggested peak pressure of at least 75 mm Hg (c 3, ll 56-61; c 3, l 66 – c 4, l 5), read to be inclusive of the ranges of 20 mm Hg to 100 mm Hg, and 25 mm Hg to 80 mm Hg. The cuff inherently corresponds to a cuff used for blood pressure measurements, as blood pressure cuffs operate at about 60 mm Hg. (See cited references)

As related to claim 7, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (c 3, l 53 – c 4, l 8).

As related to claim 8, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (c 3, l 66 – c 4, l 8).

As related to claim 10, the chamber is filled at least every 20 seconds or three times a minute (c 3, l 66 - c 4, l 5).

As related to claim 11, the chamber is filled at least every 20 seconds or 15 times in five minutes (c 3, l 66 - c 4, l 5).

As related to claim 12, the cuff and pump can be uncoupled when the inlet 19 is disconnected from the pump and associated conduit (figure 1 and 1A and c 3, ll 53-53).

As related to claim 13, the readily portable medical appliance for stimulating flow of body fluids, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction

of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As related to claim 14, the method to use the readily portable medical appliance for stimulating the flow of body fluid, includes applying a cuff (14) with a single chamber (15) to an extremity and intermittently pressurizing the cuff using a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As related to claim 15, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (c 3, l 53 – c 4, l 8).

As related to claim 16, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (c 3, l 66 – c 4, l 8).

As related to claim 17, the chamber is filled at least every 20 seconds or three times a minute (c 3, l 66 - c 4, l 5).

As related to claim 18, the chamber is filled at least every 20 seconds or 15 times in five minutes (c 3, l 66 - c 4, l 5).

As discussed in previous fourteen paragraphs of this action, Gardner et al. disclose the claimed invention except for the generator being secured to clothing.

Barak et al. teaches pneumatic compression using a miniature pressure generator secured to clothing, a belt, for the purpose enabling the patient to gain uninterrupted compression treatments while enjoying freedom of movement. It would have been obvious to one having ordinary skill in the art at the time of the invention to have secured a miniature pressure generator to clothing in the Gardner et al. system in order to create an easy to use, easy to handle, user friendly system that accommodates the need for movement and enables consistent compression treatments so the treated condition improves as rapidly as possible and is effectively maintained at an optimum level (figure 1; col. 2 @ 8-31).

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Barak et al. (US 6494852) and further in view of Raines et al. (US 6152881). As discussed in paragraph 2 of this action, modified Gardner et al. disclose the claimed invention except for the pressure generator being a roller pump.

Raines et al. disclose a method to characterize blood flow using a blood pressure cuff and teach that it is known to pressurize the cuff using a positive displacement pump (101) (figure 4 and c 15, ll 1-6). A roller pump is a type of positive displacement pump. Absent any teaching of criticality or unexpected results for the specific type of pump used, substitution of a positive displacement pump for a roller pump would have been an obvious design choice. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical appliance as taught by modified Gardner et al., with the roller pump, as taught by Raines et al. to specify a type of pump known in the art that effectively pressurizes a blood pressure cuff.

4. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view or Barak et al. (US 6494852) in view of Harada et al. (US 4928701). As discussed in paragraph 2 of this action, modified Gardner et al. disclose the claimed invention except for:

- a pressure control means to connect the cuff to the atmosphere when the cuff is overpressured (claim 4),
- the pressure control means comprising an outlet valve / overpressure outlet forming an overpressure outlet (claim 5),
- the pressure control means comprising a restrictor in a conduit and a stopper as a function of the pressure in the inlet and outlet of the restrictor (claim 6), and
- a controller which switches the generator ON/OFF to pressurize the cuff (claim 7).

Harada et al. disclose a method and apparatus for monitoring blood pressure and teach that it is known to provide a controller that switches the generator ON/OFF to pressurize the cuff and to provide a pressure control means that contains an outlet valve / overpressure outlet, a restrictor in a conduit, and a stopper so the cuff is connected to the atmosphere when the cuff is overpressured. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical appliance as taught by modified Gardner et al., with the following elements as taught by Harada et al.:

- a central processing unit (24), read as a component of the pressure control means, to connect the cuff (10) to the atmosphere when the cuff (10) is overpressured, read as when the pressure exceeds the peak pressure or the time period for inflation is

exceeded (claim 4) to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1; c 6, ll 7-10 and 16-25),

- an additional pressure control means component, a rapid deflation port (16b), read as the outlet valve / overpressure outlet (claim 5), to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1 and c 6, ll 7-10),
- further pressure control means components: a directional control valve (16), read as the restrictor, in a conduit (19) and the position selector in the control valve (16), read as a stopper (claim 6) to enable the selection by the controller to inflate or deflate the cuff (c 5, l 57 – c 6, l 10; c 6, ll 1 16-25) and
- a controller (24) which switches the generator ON/OFF to pressurize the cuff (claim 7) to enable the cuff to be inflated and deflated (c 6, ll 16-25) .

Drawings

5. The original drawings were located in the application.

6. Figures 1 and 4 are objected to under 37 CFR 1.83(a) because the rectangular boxes/ circles are not labeled as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Correction is required.

Other Prior Art Cited

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 3552381 to Burns teaches blood pressure cuffs operate at 60 mm Hg. (c 3, ll 71-75)

US 4862895 to Yamasawa et al. teach a roller pump can be used to pressurize a blood pressure cuff. (c 1, ll 54-61)

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/20/03

Angela D. Sykes

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